

1 Ramon Rossi Lopez - rlopez@lopezmchugh.com  
2 (California Bar Number 86361; admitted *pro hac vice*)  
3 Lopez McHugh LLP  
4 100 Bayview Circle, Suite 5600  
5 Newport Beach, California 92660  
6 949-812-5771

7 Mark S. O'Connor (011029) – mark.oconnor@gknet.com  
8 Gallagher & Kennedy, P.A.  
9 2575 East Camelback Road  
10 Phoenix, Arizona 85016-9225  
11 602-530-8000

12 *Co-Lead/Liaison Counsel for Plaintiff*

13 UNITED STATES DISTRICT COURT

14 DISTRICT OF ARIZONA

15 In Re Bard IVC Filters Products  
16 Liability Litigation

17 SHERR-UNA BOOKER, an individual,

18 Plaintiff,

19 v.

20 C.R. BARD, INC., a New Jersey  
21 corporation and BARD PERIPHERAL  
22 VASCULAR, an Arizona corporation,

23 Defendants.

24 No. MD-15-02641-PHX-DGC

25 **PLAINTIFF'S RESPONSE TO  
26 DEFENDANTS' MOTION  
27 JUDGMENT AS A MATTER OF  
28 LAW**

(Assigned to the Honorable David G.  
Campbell)

**(Oral Argument Requested)**

Bard's Rule 50(b) motion for judgment as a matter of law should be denied. Viewed in the light most favorable to Ms. Booker, there was substantial evidence that if Bard had disclosed to her doctors what it knew about the risks of her filter it is more likely than not that Ms. Booker would have received a different filter or would have had her filter removed before it fractured and damaged her heart. And the jury properly considered evidence regarding the G2 design and Bard's response to Recovery filter failures to determine that there was clear and convincing evidence warranting punitive damages.<sup>1</sup>

## **MEMORANDUM OF POINTS AND AUTHORITIES**

### **I. STANDARD OF REVIEW**

Under Federal Rule of Civil Procedure 50(b), the standard for review of the evidence is similar to the standard for deciding a motion for summary judgment. The Court "may not make credibility determinations or weigh the evidence," but "must view the evidence in the light most favorable to the nonmoving party . . . and draw all reasonable inferences in that party's favor." *EEOC v. Go Daddy Software, Inc.*, 581 F.3d 951, 963 (9th Cir. 2009) (citation and internal quotation omitted). A Rule 50(b) motion must be denied and "the jury's verdict must be upheld if there is evidence adequate to support the jury's conclusion, even if it is also possible to draw a contrary conclusion." *Id.* (citation and internal quotation omitted). When an argument is not made under Rule 50(a) but is raised for the first time under Rule 50(b), then "if there is any evidence to support the jury's verdict it must be upheld." *Id.* (same omissions). The jury's verdict can be overturned only where "the evidence permits only one reasonable conclusion, and that conclusion is contrary to the jury's verdict." *Id.* at 963 (same omissions).

### **II. ARGUMENT**

#### **A. Ms. Booker Presented Substantial Evidence that Her Injury Would Have Been Avoided if Bard Had Warned Doctors About G2 Failures.**

Bard erects strawman arguments that Ms. Booker must show that the risks associated with her filter were significantly greater than the risks of an alternative filter,

---

<sup>1</sup> Plaintiff incorporates by reference the trial transcript, depositions played into evidence, exhibits entered into evidence, and Plaintiff's response to Bard's motion for a new trial.

1 that she was required to provide expert testimony of a warning that would have been  
 2 appropriate, and that she must have evidence that Dr. D'Ayala would have read a proposed  
 3 alternative warning and used a different filter. Each of these arguments fail.

4 While Ms. Booker presented substantial evidence of each element that Bard claims  
 5 is required, Bard ignores the fact that substantial evidence, when taken as a whole,  
 6 established that Bard failed to provide an adequate warning to Ms. Booker's treating  
 7 physicians and, had an adequate warning been provided, more likely than not she would  
 8 have received a different filter or removed her G2 filter earlier. As detailed below, Ms.  
 9 Booker presented substantial evidence that:

- 10     ■ [REDACTED] <sup>2</sup>
- 11     ■ this new failure mode of caudal migration led to a cascade of failures;<sup>3</sup>
- 12     ■ the design changes Bard made to the Recovery filter in response to its  
       unexpected migration problem were not tested with a clinical trial, or a caudal  
       migration bench test, but only finite element analysis;<sup>4</sup>
- 13     ■ [REDACTED] <sup>5</sup>
- 14     ■ when designing the G2 filter, Bard made no attempt to reduce tilting or  
       perforation;<sup>6</sup>
- 15     ■ [REDACTED]
- 16     ■ [REDACTED], which had the same indication as Ms.  
       Booker's filter;<sup>7</sup>
- 17     ■ t [REDACTED] <sup>8</sup>
- 18     ■ this [REDACTED] <sup>9</sup>

---

23     <sup>2</sup> E.g., Ex. K, Trial Ex. 2248, p. 8; Ex. A, Trial Tr., 697:7-698:19, 705:16-707:19, 805:10-807:1,  
 24     828:13-20, 831:23-833:24, 834:19-836:8, 847:8-15, 873:11-22.

25     <sup>3</sup> E.g., Ex. A, Trial Tr., 213:1-6, 251:21-253:5, 679:3-680:9.

26     <sup>4</sup> E.g., Ex. A, Trial Tr. 205:6-15, 243:3-15, 281:23-282:2, 1099:1-1100:1, 2372:24-2373:2.

27     <sup>5</sup> Ex. L, Trial Ex. 1517, p. 49.

28     <sup>6</sup> Ex. A, Trial Tr., 195:10-18.

29     <sup>7</sup> See Ex. K, Trial Ex. 2248, p. 20.

30     <sup>8</sup> Ex. B, Trial Tr., 379:9-10, playing Ciavarella Dep. Tr., 131:16-23.

31     <sup>9</sup> See Ex. K, Trial Ex. 2248, p. 5-6.

32     <sup>10</sup> Ex. A, Trial Tr., 864:24-865:5.

- 11
- the marketing materials were inaccurate and the G2 performed worse than its predicate device;<sup>12</sup>
  - doctors receive information from manufacturers, including Bard, through channels other than the instructions for use, including marketing materials, and sales representatives;<sup>13</sup>
  - doctors expected the G2 to have improved safety or efficacy as represented in the marketing materials, to stay in place for a patient's entire life, and that the acceptable rate for a serious risk is 1 failure in one million;<sup>14</sup>
  - when various doctors learned about or experienced problems with the G2 filter, they stopped using Bard products;<sup>15</sup>
  - the sales representatives responsible for Ms. Booker's territory did not provide any of this information because they generally provide information only about random controlled clinical trials and they did not have this information;<sup>16</sup>
  - the instructions for use associated with Ms. Booker's filter were inadequate because they did not disclose that failures were occurring at rates higher than the Recovery and SNF filter;<sup>17</sup> and
  - Ms. Booker's implanting physician relied on the IFU and on sales representatives (including Bard's) and he relied on information about frequency and severity of failures in making his prescribing recommendations.<sup>18</sup>

Evidence that Bard had material information about the performance and failures of the G2 filter, and that this was the type of evidence that doctors, generally, would want to know in making treatment decisions, is sufficient for a jury to make the reasonable inference that Ms. Booker's implanting physician, Dr. D'Ayala, would have discussed these issues with Ms. Booker; chosen a different, safer filter; advised her to have the filter removed; or would have advised her to be medically monitored for filter failures.

*Placencia v. I-Flow Corp.*, No. CV10-2520 PHX DGC, 2012 U.S. Dist. LEXIS 165618, at \*\*7-10 (D. Ariz. Nov. 20, 2012) (denying motion for summary judgment where plaintiff presented evidence, in part, that company was aware of reports of the injury at issue);

---

<sup>11</sup> Ex. M, Trial Ex. 5290.

<sup>12</sup> See, e.g., subsection A., below.

<sup>13</sup> E.g., Ex. A, Trial Tr. 676:25-677:4; Ex. C, Trial Tr., 897:18, playing D'Ayala Dep. Tr. 32:19-33:3; Ex. D, Trial Tr., 1272:1-2, playing Altonaga Dep. Tr. 72:11-73:23.

<sup>14</sup> Ex. A, Trial Tr., 847:8-15.

<sup>15</sup> E.g., Ex. A, Trial Tr., 698:8-19.

<sup>16</sup> Ex. E, Trial Tr., 1273:8-9, playing Ferrara Dep. Tr. 250:22-283:19.

<sup>17</sup> E.g., Ex. A, Trial Tr., 829:2-23

<sup>18</sup> Ex. C, Trial Tr. 897:18, playing D'Ayala Dep. Tr. 21:21-24:5, 47:4-7.

1     *Goldin v. Zimmer, Inc. (In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.)*, No. MDL  
 2     No. 2272, 2017 U.S. Dist. LEXIS 2480, at \*\*126-131 (N.D. Ill. Jan. 3, 2017) (denying  
 3     motion for summary judgment where plaintiff presented evidence that pharmaceutical  
 4     warning was too general, and defendant failed to properly test its product).

5                 Thus, substantial evidence supports the jury's verdict that Bard was negligent in  
 6     failing to adequately warn physicians of the dangers associated with the G2 and that its  
 7     negligence was a cause of Ms. Booker's damages. Yet, even if Bard's inappropriately  
 8     narrow view of the evidence is considered, a careful analysis of the information presented  
 9     to the jury belies Bard's arguments and confirms that the evidence presented was sufficient  
 10    for the jury to support the jury's verdict. Each of Bard's contentions are addressed in turn.

11                 **1.     Evidence that G2 failures were significantly higher than other filters.**

12                 Ms. Booker presented substantial evidence to support the jury's finding that the G2  
 13    had a risk of failure and complications that was significantly higher than that of other  
 14    filters. [REDACTED]

15 [REDACTED]  
 16 [REDACTED]  
 17 [REDACTED] In comparison, reported migrations for SNF were 0.0% and for Recovery were

18 0.01%.<sup>19</sup> [REDACTED]  
 19 [REDACTED] and without multiplying to calculate a true failure rate, Bard concluded that  
 20 the 0.09% events reported constituted an "unacceptable risk."<sup>20</sup>

21                 Ms. Schultz testified that a product is adulterated if it fails to meet its minimum  
 22 safety specification and Bard understood that the G2 filter was not performing as expected

24 \_\_\_\_\_  
 19 Ex. K, Trial Ex. 2248, p. 5-6.

25     <sup>20</sup> *Id.* at 8.

26     <sup>21</sup> [REDACTED]

27     [REDACTED] x. N, Trial Ex. 5560, p. 24.

28     <sup>22</sup> Ex. K, Trial Ex. 2248, p. 20.

[REDACTED] . Ex. O, Trial Ex. 2052, p. 18.

1 or required.<sup>23</sup> While Bard continued to tell the public that everything was fine with its  
 2 filters, on September 25, 2007, Bard's consultant advised it that the draft EVEREST final  
 3 study report contained "the unsupported regulatory statement that . . . the EVEREST Trial  
 4 demonstrat[ed] substantial equivalence to similar devices, which it obviously didn't do."<sup>24</sup>

5 Thus, the jury could reasonably infer that if Bard determined that its filter was not  
 6 substantially equivalent to its predicate—the Recovery—or the SNF, then its failure to  
 7 communicate this critical information to doctors constituted a breach of its duty to warn.

8 Bard's contention that Dr. Grassi's testimony established an uncontested "norm"  
 9 relies on a false premise and is untrue in any event. The jury could reasonably conclude  
 10 that it was improper to compare Bard's *reported* adverse event rates with the purported  
 11 norms that to which Dr. Grassi testified, that an appropriate comparison would be proper  
 12 only after multiplying reported rates by 20 to 100, or that Dr. Grassi's testimony and the  
 13 document he testified about should not be afforded any weight. Jury Instructions [Doc.  
 14 10589] at 6, 7 (Jury may give evidence whatever weight it chooses and may accept or  
 15 reject evidence from witnesses); *Reeves v. Sanderson Plumbing Prods.*, 530 U.S. 133, 152-  
 16 53 (2000); *Wolf v. Reynolds Elec. & Eng'g Co.*, 304 F.2d 646, 648-49 (9th Cir. 1962).

17 Moreover, Bard's argument is based on a false premise: Dr. Grassi did not testify  
 18 that the reported rates of various failures established a "norm."<sup>25</sup> He testified that the  
 19 reported rates provided information about permanent, not retrievable filters, that thresholds  
 20 were intended to trigger interventional radiologists to conduct "quality assurance," and that  
 21 they were not intended as thresholds; rather, "[t]he purpose . . . of the guidelines document  
 22 was to educate, inform, and basically summarize information."<sup>26</sup>

---

23 Ex. F, Trial Tr., 1270:11, playing Schulz Dep. Tr. 168:8-16, 1785:2-9. Mr. Ganser similarly  
 24 testified that an adulterated product may not be marketed, and therefore, a product must maintain  
 25 substantial equivalence throughout the life of the product. Ex. G, Trial Tr., 1274:24-25, playing  
 26 Ganser Dep. Tr. 46:1-5, 50:11-24; *see also e.g.* Ex. A, Trial Tr., 1693:19-20 (Mr. Van Vleet  
 testifying that "if [a product] is adulterated or misbranded, it's illegal to be sold").

24 Ex. P, Trial Ex. 2252, p. 4. Natalie Wong [REDACTED]

27 [REDACTED] Ex. H, Trial Tr., 648:10, playing Wong Dep. Tr. 147:22-148:4, 185:6-9.

28 <sup>25</sup> See, generally, Ex. A, Trial Tr. 1966:6-1985:23.

<sup>26</sup> Ex. A, Trial Tr. 1968:18-23, 1971:22-1972:5, 1979:11-18.

Even if his testimony that these rates were well known to interventional radiologists was accepted by the jury (and there was no requirement the jury had to or did accept such testimony), the testimony only relates to early permanent filters.<sup>27</sup> It provides *no* information about what Dr. D’Ayala knew about the G2 filter in particular, or how its failures compared to those of the SNF and Recovery filters. The Grassi testimony does not contradict the evidence that the G2 filter failed at a higher rate than available alternatives. Indeed, Dr. Grassi testified that reported rates of “zero to 50 percent . . . would include the Bard G2” filter,<sup>28</sup> while later iterations of the document on which Dr. Grassi relied indicated that filter penetration occurred in up to 100% of filters.<sup>29</sup> In this regard, Dr. Grassi agreed with the common sense proposition that he or “any other reasonable interventional radiologist would not put a filter in that has a clinically significant penetration rate of 100 percent.”<sup>30</sup> Dr. Grassi testified that the SIR articles “did not imply that rates in that range are fine or acceptable or okay. We simply said that those were trackable events and that responsible individuals should look at any adverse event, trigger a review, and do a quality assurance monitoring to make sure that they understand some of the root causes behind such a serious problem.”<sup>31</sup>

Dr. Grassi’s testimony refutes Bard’s contention that the rates reported in the papers established a norm or a threshold because he agrees that failures within the ranges specified would not be acceptable. Dr. Grassi’s testimony did not compare reported rates, entered as evidence in this case, with rates from clinical trials and other studies that he

---

<sup>27</sup> The sole testimony on purported physician knowledge was more limited than Bard represents. Dr. Grassi answered affirmatively to the question, “these complications and trackable events that you reported about in the SIR guidelines, were they known to you in the medical community prior to developing those guidelines?” Ex. A, Trial Tr. 1977:4-8. The “medical community” was not limited in definition, nor was the qualifier “well known” used.

<sup>28</sup> Ex. A, Trial Tr. 1985:9-12.

<sup>29</sup> Ex. A, Trial Tr. 1983:14-18.

<sup>30</sup> Ex. A, Trial Tr. 2009:11-16.

<sup>31</sup> Ex. A, Trial Tr. 1995:15-23. This testimony merely establishes that there were published articles, many of which referred to permanent filters manufactured before retrievable filters were on the market, in which some doctors reported high failure rates in some filters. It says nothing about what doctors expected of the best filters, or the ones currently on the market.

1 used. Further, Dr. Grassi did not testify that doctors knew about the seriousness of G2  
 2 migration, tilt, perforation, and fracture as compared to other filters. Dr. Hurst testified that  
 3 this information was important, and Drs. Hurst and Muhercke both testified that these  
 4 failures were more dangerous in the G2 filter than in the SNF.<sup>32</sup>

5 The jury could also reasonably have considered Bard's bench testing, including tests  
 6 that it ran on the Recovery filter but did not repeat with the G2 filter, as evidence that Bard  
 7 knew about potentially dangerous or even fatal problems with the G2 which required  
 8 additional warnings. For example, migration resistance testing on the Recovery filter  
 9 showed that when hooks were removed, it was unable to withstand the pressures expected  
 10 in the vena cava at 28 mm.<sup>33</sup> [REDACTED]

11 [REDACTED]<sup>34</sup> The test results showed  
 12 that while the SNF only migrated at pressures above 100 and the Tulip filter didn't migrate  
 13 until pressures above 200, the G2 filter migrated at pressures below 50 at all tested IVC  
 14 sizes.<sup>35</sup> These lower G2 filter results were found to be statistically different from the SNF,  
 15 Tulip, and Optease filters at all IVC diameters.<sup>36</sup>  
 16 [REDACTED]

17 [REDACTED] Bard's medical director asked:  
 18 "The G2 is a permanent filter, we also have one (the SNF) that has virtually no complaints  
 19 associated with it. Why shouldn't doctors be using that one rather than the G2?"<sup>37</sup>  
 20

---

<sup>32</sup> Ex. A, Trial Tr. 682:14-683:5, 847:8-15, 852:10 - 853:12.

<sup>33</sup> Ex. Q, Trial Ex. 2065, p. 5.

[REDACTED] Ex. A., Trial Tr. 319:10-14. While Dr. Altonaga testified that the IVC can expand up to 50%. Ex. D, Trial Tr. 1272:1-2, placing Altonaga Dep. Tr. 142:10-13.

<sup>34</sup> Ex. A, Trial Tr. 241:9-13.

<sup>35</sup> Ex. R, Trial Ex. 1575, at 13.

<sup>36</sup> *Id.* at 14-16.

<sup>37</sup> Ex. S, Trial Ex. 991, p. 1. In February 2006, Bard conducted a Health Hazard Evaluation of G2 caudal migration and concluded that this type of failure had not been reported at these rates in the literature, and the severity was "Critical" because filters would lose the ability to prevent clots. Ex. T, Trial Ex. 1221, p. 1. [REDACTED]

1           With respect to the Recovery filter, in February 2004, Ms. Hudnall wrote:  
 2           I must strongly caution against emphasizing Recovery's ability to center in  
 3           the cava to the point where it is the focus of the product's positioning. We  
 4           knew very little about the long-term clinical performance of this device when  
 5           we launched.<sup>38</sup>  
 6           Bard's knowledge of Recovery performance is relevant to the G2 filter because  
 7           when Bard made design changes to Recovery and developed the G2 filter, [REDACTED]  
 8           [REDACTED]  
 9           [REDACTED] .<sup>39</sup> Ms. Wong, who was a quality engineer manager for  
 10          filters from 2002 to 2012, testified that Bard never determined a root cause for fracture,  
 11          migration, perforation, or tilt.<sup>40</sup> All of this evidence supports the jury's finding that Bard  
 12          was negligent in failing to adequately warn about the dangers of the G2.

13           **2. Evidence of alternative warning.**

14           Although Ms. Booker presented substantial evidence—including expert testimony  
 15          and statements from Bard's employees—of an appropriate warning that the jury could  
 16          reasonably conclude had not been communicated, such specific evidence is not required.  
 17          Bard has cited no Georgia state appellate court decision that requires expert opinion or a  
 18          specific alternative warning. The case Bard relies on, *Nolley v. Greenlee Textron, Inc.*, No.  
 19          1:06-CV-228-MHS, 2007 U.S. Dist. LEXIS 97402, at \*18 (N.D. Ga. Dec. 6, 2007), stands  
 20          for the proposition that in the absence of expert testimony on a complicated issue, a party  
 21          may fail to establish proximate cause. This issue arises in the prescription drug context,  
 22          where it can be more difficult to prove that the product has caused an injury.<sup>41</sup> Moreover,

---

23          <sup>38</sup> Ex. U, Trial Ex. 545. Bard also determined in a December 2004 Health Hazard Evaluation that:  
 24           Reports of death, filter migration (movement), IVC perforation, and filter fracture  
 25           associated with Recovery filter were seen in the MAUDE database at reporting  
 26           rates that were 4.6, 4.4, 4.1, and 5.3 higher, respectively, than reporting rates for all  
 27           other filters. These differences were all statistically significant. . . . Recovery filter  
 28           had the lowest mean migration resistance (50 mmHg). Ex. V, Trial Ex. 1032.

29          <sup>39</sup> Ex. I, Trial Tr., 649:24, playing Hudnall Dep. Tr. 358:24-359:4.

30          <sup>40</sup> Ex. H, Trial Tr., 648:10, playing Wong Dep. Tr. 32:23-33:20.

31          <sup>41</sup> *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig.*, 227 F. Supp. 3d  
 32           452, 469 (D.S.C. 2017) is inapposite for this reason.

1 Nolley relied on an Eastern District of Pennsylvania case, *Pineda v. Ford Motor Co.*, No.  
 2 04-3359, 2006 U.S. Dist. LEXIS 91992, 2006 WL 3762015 at \*2 (E.D. Pa. Dec. 19, 2006),  
 3 that was reversed by the Third Circuit. *Pineda v. Ford Motor Co.*, 520 F.3d 237, 248 (3d  
 4 Cir. 2008) (rejecting overly narrow focus on expert's failure to propose an alternative  
 5 warning and finding engineer's opinion that warning was inadequate sufficient).

6 Even so, the evidence on this point is substantial. For example, Doctors Hurst and  
 7 Muhercke testified about information that they believed should have been included in the  
 8 instructions for use or communicated to doctors in other ways.<sup>42</sup> The jury could reasonably  
 9 have determined, based on the 2008 instructions for use,<sup>43</sup> that the instructions for Ms.  
 10 Booker's filter inadequately warned about the EVEREST clinical trial adverse events.

11       **3. Evidence of proximate cause.**

12       The jury reasonably found proximate cause because Ms. Booker presented  
 13 substantial evidence that Dr. D'Ayala was not aware of the risks associated with the G2  
 14 filter and would have made a different treatment decision had the information been  
 15 provided to him, including taking steps to remove the filter after it was implanted:<sup>44</sup> "With  
 16 regards to the Bard filter, would I have used a different device if I knew at the time that the  
 17 Bard filter was not ideal or as good as some of the other implants? The answer would have  
 18 to be yes... I would have used a different filter if there was a different filter that I knew of  
 19 that was better, in terms of its safety profile."<sup>45</sup> He also testified it was "unlikely" that he  
 20 would have used a G2 if he knew there was a 12% probability of fracture with the filter.<sup>46</sup>

---

21       <sup>42</sup> Ex. A, Trial Tr., 697:7-698:19, 705:16-707:19, 805:10-807:1, 828:13-20, 831:23-833:24,  
 22 834:19-836:8, 847:8-15, 873:11-22.

23       <sup>43</sup> Ex. W, Trial Ex. 5283, p. 2-3 (containing limited information about the EVEREST trial).

24       <sup>44</sup> Ex. C, Trial Tr., 897:18, playing D'Ayala Dep. Tr. 126:19-127:3.

25       <sup>45</sup> *Id.*, playing D'Ayala Dep. Tr. 62:25-63:9.

26       <sup>46</sup> *Id.*, playing D'Ayala Dep. Tr. 70:9-20. Contrary to Bard's assertion that "plaintiff's counsel  
 27 never even identified the date or source of the alleged information providing the premise for these  
 28 questions, much less produced evidence to substantiate them," Mot. at 6, Dr. D'Ayala was  
 presented with the Nicholson paper at his deposition, (*Id.*, playing D'Ayala Dep. Tr. 64:9-67:10,  
 126:16-21) and Mr. Van Vleet testified that the Nicholson paper reported 13 fractures out of 80  
 patients (i.e., over 16%). Ex. A, Trial Tr. 1685:18-1686:13. Moreover, Dr. Morris, Bard's expert,  
 testified that out of 37 G2 filters analyzed in one study, there were 11 instances of filter fragments  
 embolizing to the lungs and 22 to the heart. Ex. A, Trial Tr. 2108:9-23, 2109:8-22. While the data

1 Dr. D'Ayala further testified that he stopped using the G2 filter based on adverse  
 2 event reports, after "it was becoming clear that there were numerous reports in the  
 3 literature of filter fragments and filter migration," with the G2 filter.<sup>47</sup> The jury could  
 4 reasonably infer from this testimony that Dr. D'Ayala understood that adverse event  
 5 reports represented a fraction of the true failure rate and the he and they should multiply by  
 6 20-100 to calculate a true failure rate from the reported rates entered into evidence.

7 Dr. D'Ayala also testified that Recovery information would have been relevant to  
 8 his decision to use the G2 filter.<sup>48</sup> Doctors Hurst and Muehrcke testified that the G2's IFU  
 9 did not adequately disclose risk information important to them and reasonable doctors.<sup>49</sup>

10 Ms. Booker also presented evidence from which the jury could reasonably conclude  
 11 by a preponderance of evidence that the filter would have been retrieved sooner if her  
 12 doctors had been given additional warnings. She testified that when she went for follow up  
 13 treatment with her doctors during her cancer treatment, she asked them about the filter  
 14 because she was concerned about a foreign object in her body.<sup>50</sup> Further, Dr. Kang testified  
 15  
 16

---

17 that Mr. Van Vleet and Dr. Morris testified about were published after Ms. Booker's filter was  
 18 implanted, the jury could reasonably infer based on the evidence from the short follow-up in the  
 19 EVEREST trial and the bench tests results that the Nicholson data reflected a long-term fracture  
 rate that Bard would have found if it had conducted proper bench tests and clinical trials.

20 <sup>47</sup> Ex. C, Trial Tr., 897:18, playing D'Ayala Dep. Tr. 31:13-32:1.

21 <sup>48</sup> When asked if he would have used a different filter if he knew all the information that the  
 22 Recovery investigations revealed he responded, "Difficult to say with certainty. It would depend  
 23 upon what other filters we had at the time and what their problems would have been. But it would  
 24 have been a very important piece of information, as far as making decisions regarding this or any  
 25 other patient, yes." *Id.*, playing D'Ayala Dep. Tr. 63:10-64:2. He was never told by his sales rep  
 26 that there was a 530% higher fracture rate over other filters on the market for the Recovery or a  
 27 1200% higher risk of death from Recovery fracture and embolization to the heart. He testified he  
 28 would have liked to have known this information in 2004-2005 before he implanted Ms. Booker  
 with the G2 filter. *Id.*, playing D'Ayala Dep. Tr. 34:7-35:2. He also testified that the information  
 contained in the 2004 health hazard evaluation from David Ciavarella, M.D., vice president of  
 clinical affairs at Bard, showing higher fracture rates in the Recovery compared to other filters  
 would have been important information for him to have. *Id.*, playing D'Ayala Dep. Tr. 36:11-  
 37:20.

<sup>49</sup> Ex. A, Trial Tr., 697:7-698:19, 705:16-707:19, 805:10-807:1, 828:13-20, 831:23-833:24,  
 834:19-836:8, 847:8-15, 873:11-22.

<sup>50</sup> Ex. A, Trial Tr. 1198:4-15.

1 that he would have wanted to know about a 10% fracture rate, and he would not have used  
 2 the G2 filter if Bard had told him this.<sup>51</sup>

3 Viewed in its entirety, the evidence supports the jury's verdict.

4 **B. Clear and Convincing Evidence Supports the Punitive Damages Award.**

5 Bard's argument regarding punitive damages fails for two reasons. First, Bard's  
 6 argument that the scope of evidence must be limited misconstrues the relevance of  
 7 Recovery and design evidence to the failure to warn claim. Second, even considering only  
 8 evidence that falls within Bard's unduly narrow scope, Ms. Booker presented substantial  
 9 evidence of conduct warranting punitive damages.

10 **1. The jury properly considered the evidence presented.**

11 Bard's reliance on *State Farm* and *Philip Morris* for the proposition that Recovery  
 12 migration death evidence cannot be considered when evaluating the sufficiency of the  
 13 evidence is misplaced because the Court in those cases was focused on the amount of  
 14 damages and was influenced by the financial—rather than physical—nature of the  
 15 underlying injuries at issue. *See State Farm Mutual Automobile Insurance Co. v.*  
 16 *Campbell*, 538 U.S. 408, 419-22 (2003); *Philip Morris USA v. Williams*, 549 U.S. 346, 353  
 17 (2007). In *State Farm*, the Court was concerned about the *amount* of the punitive award, an  
 18 issue not raised here by Bard. *State Farm*, 538 U.S. at 419-420 (“While we do not suggest  
 19 there was error in awarding punitive damages . . . a more modest punishment for this  
 20 reprehensible conduct could have satisfied the State’s legitimate objectives.”). The Court  
 21 noted that out-of-state conduct—even if lawful—can be probative “when it demonstrates  
 22 the deliberateness and culpability of the defendant’s actions,” so long as there is a nexus to  
 23 the specific harm suffered by the plaintiff.” *Id.* at 422. Thus, “evidence of repeated  
 24 misconduct of the sort that harmed” the plaintiffs in *State Farm* was proper even if it was  
 25 merely too limited in that case to warrant the amount of damages awarded. *Id.* at 422-23  
 26 (noting “evidence of other acts need not be identical”). The Court also indicated that  
 27 punitive damages awards are more reasonable where, as here, a physical harm is involved,

---

28 <sup>51</sup> Ex. J, Trial Tr., 926:22, playing Kang Dep. Tr. 55:9-56:1.

1 describing the compensatory damages award of \$1 million for economic harm as  
 2 “substantial” and “complete.” *Id.* at 426 (“The harm arose from a transaction in the  
 3 economic realm, not from some physical assault or trauma; there were no physical  
 4 injuries.”); *see also BMW of N. Am. v. Gore*, 517 U.S. 559, 576 (1996) (“The harm . . .  
 5 inflicted . . . was purely economic in nature. . . . [Defendant’s] conduct evinced no  
 6 indifference to or reckless disregard for the health and safety of others.”).

7 Similarly, in *Philip Morris*, the defendant argued the punitive damages award was  
 8 excessive in a case where smoking allegedly caused a death. *Philip Morris USA v.*  
 9 *Williams*, 549 U.S. at 351. While the Court declined to consider directly whether the award  
 10 was excessive, *id.* at 358, it focused on “the Constitution’s procedural limitations” in how a  
 11 jury may calculate an amount for punitive damages. *Id.* at 353.

12 The Court and Phillip Morris agreed that conduct may be considered in deciding  
 13 reprehensibility, and drew a distinction that limits are placed when considering the *amount*  
 14 of an award, not *whether* there should be an award:

15 Philip Morris, in turn, does not deny that a plaintiff may show harm to others in  
 16 order to demonstrate reprehensibility. Nor do we. Evidence of actual harm to  
 17 nonparties can help to show that the conduct that harmed the plaintiff also posed a  
 18 substantial risk of harm to the general public, and so was particularly reprehensible.  
*Id.* at 355. Based on this, and a request for a limiting instruction that the court below  
 19 denied, the Court asked: “How can we know whether a jury, in taking account of harm  
 20 caused others under the rubric of reprehensibility, also seeks to punish the defendant for  
 21 having caused injury to others?” *Id.* at 357. In answer, the Court held that “state courts  
 22 cannot authorize procedures that create an unreasonable and unnecessary risk of any such  
 23 confusion occurring,” and required “some form of protection in appropriate cases.” *Id.*

24 While the Court remanded for consideration of how this protection should be  
 25 implemented, it discussed the jury instructions that had been proposed by the defendant but  
 26 rejected by the trial court. Notably, the jury instruction requested by Philip Morris was  
 27 similar to Bard’s requested instruction given to the jury in this case. *Compare id.* at 356  
 28 (“you may consider the extent of harm suffered by others in determining what [the]

1 reasonable relationship is between Philip Morris' punishable misconduct and harm caused  
 2 to [plaintiff] [but] you are not to punish the defendant for the impact of its alleged  
 3 misconduct on other persons, who may bring lawsuits of their own in which other juries  
 4 can resolve their claims") *with* Joint List of Proposed Jury Instructions [Doc. 10254] at 117  
 5 *and* Jury Instructions [Doc. 10589] at 36-37 ("You may have heard evidence of other  
 6 conduct and procedures of Bard. For the purpose of punitive damages, you may not  
 7 consider evidence of any conduct of Bard that is dissimilar to that which resulted in Ms.  
 8 Booker's injury – unless such dissimilar conduct was related to the specific harm suffered  
 9 by Ms. Booker in this case."). A similar instruction denied in *Merrick v. Paul Revere Life*  
 10 *Ins. Co.*, which formed the basis of the appellate court's decision to reverse and remand for  
 11 a new trial. 500 F.3d 1007, 1015 (9th Cir. 2007). In *Merrick*, the court distinguished  
 12 between use of "'bad company' evidence . . . [which] the jury was permitted to consider . .  
 13 . when determining the reprehensibility," and evidence a jury uses when "setting an  
 14 amount of damages that includes direct punishment for harm to others." *Id.* at 1017.<sup>52</sup>

15 Because Bard does not challenge the amount of punitive damages, the above cases  
 16 are of limited relevance. Ms. Booker has shown a nexus between the conduct that harmed  
 17 her and the evidence presented, as argued above. This is not like the evidence in *State*  
 18 *Farm*, which the Court held had "nothing to do" with the case at issue. *Id.* at 424. Rather,  
 19 the Recovery and design evidence in this case has a direct nexus to the harm that occurred  
 20

---

21 <sup>52</sup> In *Gore*, the first in the Supreme Court's recent trilogy of punitive damages cases, the Court was  
 22 animated by the same issue: the *amount* of the punitive damages award, and whether it had been  
 23 calculated to punish a defendant for harm caused in other states. *Id.* at 562-63 ("The question  
 24 presented is whether a \$2 million punitive damages award . . . exceeds the constitutional limit.").  
 25 The *Gore* Court did limit the evidence that may be considered in deciding whether punitive  
 26 damages are awarded, and indicated that evidence of similar conduct is relevant and may be  
 27 considered. *Id.* at 576-75 ("Certainly, evidence that a defendant has repeatedly engaged in  
 28 prohibited conduct while knowing or suspecting that it was unlawful would provide relevant  
 support for an argument that strong medicine is required to cure the defendant's disrespect for the  
 law. . . . Our holdings that a recidivist may be punished more severely than a first offender  
 recognize that repeated misconduct is more reprehensible than an individual instance of  
 malfeasance.") (citations omitted); *see also Mack Trucks v. Conkle*, 436 S.E.2d 635, 640 (Ga.  
 1993) (holding evidence of numerous complaints of other truck frame failures "was relevant to the  
 issues of notice and punitive damages, and was properly admitted").

1 to Ms. Booker because it proves that Bard knew of the risks to Ms. Booker and consciously  
 2 disregarded them. Further, Bard has not pointed to evidence through which Ms. Booker  
 3 attempted to demonstrate the total number of people harmed by the Recovery filter or even  
 4 the G2 filter; the limited reference to other lawsuits during the trial generally came from  
 5 Bard, when asking about the compensation of Ms. Booker's experts. Moreover, "evidence  
 6 of other acts need not be identical." *State Farm*, 538 U.S. at 423. It is the risk of harm from  
 7 Bard's filters that were not fully tested that is the common theme that permits the jury to  
 8 properly consider this evidence.

9       **2. Ms. Booker presented substantial evidence from which the jury could  
 10 reasonably find punitive damages were warranted.**

11       When considering whether a plaintiff has presented evidence to prove by clear and  
 12 convincing evidence that a defendant's conduct warrants punitive damages under Georgia  
 13 law, courts consider whether there has been an "entire want of care and an indifference to  
 14 consequences." *Brown v. Starmed Staffing, L.P.*, 490 S.E.2d 503, 509 (Ga. App. 1997). For  
 15 example, where a defendant added lemon scent to its bleach product, and was aware that  
 16 this "enhanced the danger of inhalation of its fumes, yet failed to warn the user of such  
 17 dangers," the court held that punitive damages were warranted and affirmed denial of a  
 18 summary judgment motion. *Zeigler v. Clowhite Co.*, 507 S.E.2d 182, 185 (Ga. App. 1998).  
 19 Similarly, where a man experienced symptoms due to pesticide exposure at his workplace  
 20 and alleged that the pesticide company failed to apply the pesticides properly to limit  
 21 exposure, the court held: "The evidence supports a finding that [the defendant] displayed a  
 22 conscious indifference to the possible infliction of personal injury on its customers as a  
 23 result of their exposure to pesticides misapplied by [defendant's] technicians. In this case,  
 24 as in most others, a jury question was created whether clear and convincing evidence of  
 25 such conduct exists." *Orkin Exterminating Co. v. Carder*, 575 S.E.2d 664, 670 (Ga. App.  
 26 2002) (evaluating evidence under similar summary judgment standard).

27       Punitive damages were also allowed where an engineering division of a company  
 28 that manufacturers trucks repeatedly warned that the truck frame rails should be reinforced.

1     *Mack Trucks v. Conkle*, 436 S.E.2d 635, 640 (Ga. 1993). Evidence was properly admitted  
 2 of “numerous” complaints of different frame rail cracks and that the marketing division  
 3 made a decision not to reinforce the frame rails based on cost. *Id.* The court held that “that  
 4 this evidence, along with other evidence in the record, shows a ‘conscious indifference to  
 5 consequences,’ and therefore meets the ‘clear and convincing’ standard of O.C.G.A. § 51-  
 6 12-5.1 (b).” *Id.*; *see also, GM Corp. v. Moseley*, 447 S.E.2d 302, 311-12 (Ga. App. 1994)  
 7 (holding that “evidence of a knowing endangerment of all who may come in contact with  
 8 one of the 5,000,000 GM full-size pickup trucks still on the road, motivated by economic  
 9 benefit, was sufficient to support an award of punitive damages.”). Similarly, summary  
 10 judgment regarding punitive damages was denied where either a nurse or a doctor gave a  
 11 patient medication that a second doctor believed was causing a severe allergic reaction.  
 12 This was sufficient to show “an entire want of care and an indifference to consequences.”  
 13 *Brown v. Starmed Staffing, L.P.*, 490 S.E.2d 503, 509 (Ga. App. 1997) (“Wilful and  
 14 intentional misconduct is not essential.”); *see also Oglethorpe Power Corp. v. Estate of*  
 15 *Forrister*, 774 S.E.2d 755, 764 (Ga. App. 2015) (allowing punitive damage where  
 16 defendant failed to reduce power plant noise, despite lack of physical injury.)

17       The conduct here is not like that in *Heston v. Taser Int'l, Inc.* (relied on by  
 18 Defendants) because in that case the jury found that the defendant did not know of the risk  
 19 of injury (“prolonged TASER deployment”) that caused the injury forming the basis of the  
 20 punitive damages claim. 431 F. App’x 586, 589 (9th Cir. 2011) (unpublished). Here, the  
 21 jury found that Bard knew or should have known about the risks to Ms. Booker, and could  
 22 reasonably have found that Bard had actual knowledge and conscious disregard of the  
 23 risks, rising to the level of punitive conduct under Georgia law.<sup>53</sup>

---

24       <sup>53</sup> The cases cited in footnote 8 of Bard’s motion are distinguishable. In *Stone Man, Inc. v. Green*,  
 25 435 S.E.2d 205, 206 (Ga. 1993), the court reversed a punitive damages award based on nuisance  
 26 where defendant operated a mine, followed local, state, and federal law, and was allowed to  
 27 continue operating the mine. The court did not reference any allegation or argument that the  
 28 defendants consciously disregarded a severe risk of harm to others, and nuisance claims are not  
 like product liability claims in which severe injury occurred. In *Hernandez v. Crown Equip. Corp.*,  
 92 F. Supp. 3d 1325, 1357 (M.D. Ga. 2015), the court found no conscious indifference to the risk  
 of injury from a forklift because the manufacturer placed specific warnings on the forklift, which

1       All of the evidence described above is relevant to show that Bard demonstrated an  
 2 “entire want of care which would raise the presumption of conscious indifference to  
 3 consequences.” Official Code of Ga. § 51–12–5.1(b). At the time Ms. Booker’s filter was  
 4 implanted, and during the time leading up to her injury, Bard knew about serious failures  
 5 with its filters and failed to warn about them.

6       Furthermore, as explained above, the Recovery evidence is relevant to this inquiry  
 7 because it is part of the whole picture regarding what Bard knew and consciously  
 8 disregarded. Bard designed a new filter and launched it onto the public with only a pilot  
 9 test that did not assess safety (and which provided evidence of a high rate of failures).  
 10 When reports of Recovery failures started coming in, Bard changed the design, but without  
 11 a root cause analysis, without proper bench testing, and without even a pilot study (let  
 12 alone a clinical trial) to assess whether the changes worked [REDACTED]  
 13 [REDACTED]  
 14 [REDACTED] .<sup>54</sup> In Bard’s [REDACTED]  
 15 [REDACTED].<sup>55</sup>

---

16       “caution operators to keep their limbs inside the operator’s compartment” and stated that “[a] foot  
 17 or hand caught between the truck and a fixed object will be crushed or even cut off.” *Id.* at 1337.  
 18 In *Moore v. Wright Med. Tech., Inc.*, No. 1:14-CV-62, 2016 WL 1298975, at \*6 (S.D. Ga. Mar.  
 19 31, 2016), summary judgment on punitive damages was granted where the plaintiffs, in response  
 20 to the motion, “generally referenc[ed] the ‘evidence of [Defendant’s] misconduct.’” (citation and  
 21 internal quotation omitted). In *Stuckey v. N. Propane Gas Co.*, 874 F.2d 1563 (11th Cir. 1989), the  
 22 court determined that summary judgment for punitive damages was appropriate because it was  
 23 “difficult to demonstrate” that the defendant was aware of the risk at issue. *Id.* at 1569. In *Kodadek*  
 24 v. *Lieberman*, 545 S.E.2d 25, 29-30 (Ga. 2001), summary judgment was granted for a punitive  
 25 damages claim involving a needle that broke during a surgical procedure. *Id.* at 27. The doctor  
 26 immediately told the patient and his parents. The court did not grant summary judgment for  
 27 punitive damages on the allegation that the doctor misrepresented that it was safe to leave the  
 28 needle in place and the size of the needle, precisely the type of actual knowledge and conscious  
 disregard of risk complained of here. *Id.* In *Roseberry v. Brooks*, 461 S.E.2d 262, 268-69 (Ga.  
 App. 1995), “the only circumstances advanced in support” of punitive damages was an allegation  
 that the defendant failed to provide a transfusion before an abortion procedure. Unlike here,  
*Kodadek* and *Roseberry* are cases with limited evidence of a conscious disregard for risk.

<sup>54</sup> Ex. X, Trial Ex. 5303, p. 16.

<sup>55</sup> Ex. L, Trial Ex. 1517, p. 49.

[REDACTED] Ex. A, Trial Tr., 234:13-17; Ex. Y, Trial Ex. 932, p. 6 (“Lack of thorough understanding dynamics of caval anatomy.”), while Dr. Hurst testified that it would have been reasonable for Bard to have thoroughly tested and

Once the G2 was on the market, Bard continued to receive information about serious failures, and learned through statistical analyses of adverse event reports, bench tests, and the EVEREST clinical trial that the G2 filter was failing at high rates and had developed a new problem—caudal migration and the cascade of failures that followed from it. Rather than warn physicians, Bard downplayed the risks, changed [REDACTED] [REDACTED],<sup>56</sup> and updated [REDACTED]<sup>57</sup> so that it could claim that the G2 filter was substantially equivalent to its predicate. Meanwhile, the G2 Brochure made claims that were directly contradicted by the internal evidence, and Bard never updated this document.<sup>58</sup> Instead, Bard focused on its belief that “Users can be swayed by aggressive marketing even with negative clinical experience.”<sup>59</sup>

This evidence does not invite the jury to punish Bard for harm caused to others, but demonstrates Bard’s conscious disregard for the risk to Ms. Booker. Focusing only on the G2 and the evidence presented above and incorporated by reference from Plaintiff’s response to Bard’s Motion for a New Trial, there is sufficient evidence for a reasonable jury to award punitive damages.

### **III. CONCLUSION**

Bard’s Motion for Judgment as a Matter of Law should be denied because the evidence supports the jury’s finding of negligent failure to warn and punitive damages.

---

study the cava dynamics before it released the G2 filter to the market. Ex. A, Trial Tr., 821:25 to 822:3.

<sup>56</sup> Ex. X, Trial Ex. 5303, p. 21.

<sup>57</sup> Ex. A, Trial Tr. 1902:21- 1903:2; Ex. Z, Trial Ex. 2251, p. 5.

<sup>58</sup> Ex. AA, Trial Ex. 2045; Ex. BB, 1335; Ex. CC, 1336; and Ex. DD, 1337.

<sup>59</sup> Ex. EE, Trial Ex. 1053, p. 4.

RESPECTFULLY SUBMITTED this 7th day of May 2018.

## GALLAGHER & KENNEDY, P.A.

By: s/ Mark S. O'Connor

Mark S. O'Connor

2575 East Camelback Road

Phoenix, Arizona 85016-9225

LOPEZ McHUGH LLP

Ramon Rossi Lopez (CA Bar No. 86361)  
(619) 464-2888

(admitted *pro hac vice*)  
100 E. 51st St., N.Y.

100 Bayview Circle, Suite 5600  
Newport Beach, California 92660

### *Co-Lead/Liaison Counsel for Plaintiffs*

## **CERTIFICATE OF SERVICE**

I hereby certify that on this 7th day of May 2018, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ *Gay Mennuti*